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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/613,650

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Michael R. Hale

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EXAMINER

AULAKH, CHARANJIT

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 05/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/613,650	Applicant(s) HALE ET AL.	
	Examiner Charanjit S. Aulakh	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _____ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 12-17 and 23-27 is/are pending in the application.
- 4a) Of the above claim(s) 9, 14 and 16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 11, 13, 15, 17 and 23-27 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2 pages</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. According to paper filed on May 8, 2006, the applicants have elected group I without traverse for further prosecution in response to restriction requirement. The applicants have also canceled claims 11 and 18-22 and furthermore, have amended claims 1, 15, 17 and 23.

2. Claims 1-10, 12-17 and 23-27 are pending in the application. Claims 9, 14 and 16 are withdrawn from further consideration as being directed to non-elected subject matter. It is of note that group I is directed to compounds of formula (I) where compounds are represented by compounds disclosed in table 1 where G is H, R7 is H, B is absent and D represents benzyl group.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 24, 26 and 27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating an HIV virus infection using instant compounds of formula (I) alone, does not reasonably provide enablement for treating HIV virus infection using combination of instant compounds of formula (I) with any other antiviral agent. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex parte Foreman,

230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight different factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples, the state of the prior art, unpredictability and the breadth of claims.

The specification teaches inhibition of HIV-protease activity as well as antiviral activity of instant compounds in MT4 cells. However, there is no teaching in the specification regarding using instant compounds in combination with any other agent for studying antiviral activity in MT4 cells. There are no working examples present showing antiviral activity of combination of instant compounds with any other agent in MT 4 cells. There is no teaching in the specification regarding mechanism of action of other antiviral agents for antiviral activity. There is lot of speculation and unpredictability regarding outcome of the combination treatment since other antiviral agent may actually neutralize the effect of instant compounds. The instant compounds of formula (I) encompass hundreds of thousands of compounds based on the values of various variables and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in

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combination with hundreds of thousands of other antiviral compounds in MT4 cells and hence their utility for treating HIV virus infection.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 2-7, 17, 23, 24 and 27 are rejected under 35 U.S.C. 112, second paragraph; as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 5-7, for the value of variable D', the applicants have put a proviso that when R1 is -C(O)-. However, according to amended claim 1, R1 only represents -O-C(O)- and therefore, can not be -C(O)-.

In claims 2-4, the term ---each of which is optionally substituted with C3-C8 cycloalkyl--- is indefinite since it is not clear whether alkyl, alkenyl or alkynyl groups are optionally substituted or CN groups are optionally substituted or both are optionally substituted?

In claim 17, compound numbers are mentioned. However, their structures are missing in the claim.

In claim 23, the term ----detectably inhibit protease activity in a patient --- is vague and indefinite since actual intent is not clear. In order to inhibit activity in a patient, composition needs to be administered and furthermore, it is not clear how this inhibition is being assessed in vivo? The applicants are suggested to use the language --- A composition comprising a therapeutically effective amount of a compound according ---- and delete ---in an amount sufficient to detectably inhibit aspartyl protease activity in a patient -----.

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In claims 24 and 27, the term ----additional antiviral agent--- is indefinite since specific agent with defined structure is not defined. Also, in claim 27, it is not clear whether a second additional antiviral agent is being administered since method of claim 26 uses composition of claim 24 which already has an additional antiviral agent.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1, 5-8, 10, 13, 15 and 23-27 are rejected under 35 U.S.C. 102(e) as being anticipated by Freskos (U.S. Patent 6,143,747).

Freskos discloses bis-sulfonamide hydroxyethylamino retroviral protease inhibitors for treating HIV infection. The compounds 34, 37 and 38 (see table 1A in column 41) disclosed by Freskos anticipate the instant claims when alkyl group (variable D' in instant compounds) is substituted with SR₃, N(R₃)₂ and S(O)_nR₃ groups. It is of note that the proviso does not exclude these compounds since R₁ represents –O-C(O)- in the instant compounds.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 5, 6, 8, 10, 13, 15 and 23-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Freskos (U.S. Patent 6,143,747).

Freskos discloses bis-sulfonamide hydroxyethylamino retroviral protease inhibitors for treating HIV infection. The compounds 12, 14, 36, 48 and 49 (see table 1A in columns 40-43) disclosed by Freskos. differ from the instant compounds in having variable R3 (equivalent to instant variable D') as unsubstituted alkyl group instead of substituted with a halogen. However, the generic teachings of Freskos teach that variable R3 (see col. 4, lines 22-31) can also be haloalkyl. Therefore, it would have been obvious to one skilled in the art to prepare the instant compounds with variable D' as haloalkyl without losing their utility for treating HIV infection.

11. Claims 1-8, 15 and 23-27 are objected for containing non-elected subject matter.

Allowable Subject Matter

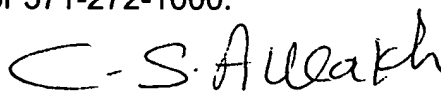
12. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie can be reached on (571)272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Charanjit S. Aulakh
Primary Examiner
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